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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,016	03/24/2001	Mark B. Lyles	068986.0107	5726

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EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/817,016

Applicant(s)

LYLES, MARK B.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-41,43,44,46-48 and 56-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41,43,44,46-48 and 56-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 19-41,43,44,46-48 and 56-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/6/04 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 41, 43-44, 47-48, and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasukawa et al. (US Pat. 5,629,186) in view of Arnold (US Pat. 4,560,504).

Yasukawa et al. teach a porous matrix and methods of its production. Fused fibrous

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ceramic materials are prepared from amorphous silica and/or alumina fibers with 2 to 12% boron nitride. The matrix may be used as a cell culture substrate, an implant material, and for chromatographic separation of blood cells (abstract). The matrix may have a density between 3.5 and 5.5 pounds per cubic foot, and the fibers may have diameters between 0.5 and 20 microns, with a diameter of between 0.5 and 5 microns in one of the preferred embodiments. For use as an implantable material, the matrix may be coated with a biocompatible material on its outer surface. For use in affinity chromatography, the fibers may be derivatized with molecules effective to bind ligand molecules passed through the matrix (Col. 1). However, the reference does not teach the use of specific biological compounds linked to the material.

Arnold teaches a system for the immobilization of antibodies, wherein an antibody or a fragment thereof is bonded to a support. The support of the reference may be a porous or semi-porous inorganic solid, including alumina and silica-alumina (Col. 6, lines 30-47).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize antibodies as taught by Arnold with the device and method of Yasukawa et al. because Arnold teaches that these molecules may be linked to surfaces of alumina or silica-alumina. In addition, Yasukawa et al. contemplate the linking of biological materials to the surfaces of their invention. Further, although Arnold does not specifically teach linking of molecules to surfaces of alumina, silica, and a fusion source, one of skill in the art would have known that the chemistry involved in linking molecules to that type of surface would be very similar to that of alumina-silica, and would have required only routine optimization. Arnold teaches that biological molecules may be linked to alumina-silica, and since the boron fusion source of the claims may comprise as little as 2% of the total surface of the material, the

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fusion source would not materially affect the surface chemistry for immobilization purposes. Furthermore, although Yasukawa does not specify the exact percentages of alumina or silica as between 1-50% and 50-98% respectively, such would have been obvious to one of ordinary skill at the time of the invention because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Also, since alumina is an optional component of the matrix, and the boron source only comprises 2 to 12% of the material, it would have been obvious to that matrix could be 88-98% silica. In addition, it would have been obvious to make a material with a density of 6 pounds per cubic foot because Yasukawa teaches a density of up to 5.5, and one would have had a reasonable expectation of success in making a material that is only a little denser because there is no reason to believe that a half-pound increase in density would adversely affect the device in any way.

5. Claims 41, 43-44, 46-48, and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyles et al. (WO 96/24631) in view of Arnold (US Pat. 4,560,503).

Lyles et al. teach dental materials comprising from about 1-50% by weight alumina, 50-90% by weight silica, and 1-5% by weight boron. In preferred embodiments, the composition may have 2.85% boron nitride. The mean pore diameter of the material is greater than 10 microns (page 20). The density of the material may be from 4-62 pounds per cubic foot (page 5). According to the reference, silanization improves the fiber to resin bond. However, the reference does not teach the use of specific biological compounds linked to the material.

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Arnold teaches a system for the immobilization of antibodies, wherein an antibody or a fragment thereof is bonded to a support. The support of the reference may be a porous or semi-porous inorganic solid, including alumina and silica-alumina (Col. 6, lines 30-47).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize antibodies as taught by Arnold with the device and method of Lyles et al. because Arnold teaches that these molecules may be linked to surfaces of alumina or silica-alumina. In addition, although Arnold does not specifically teach linking of molecules to surfaces of alumina, silica, and a fusion source, one of skill in the art would have known that the chemistry involved in linking molecules to that type of surface would be very similar to that of alumina-silica, and would have required only routine optimization. Arnold teaches that biological molecules may be linked to alumina-silica, and since the boron fusion source of the claims may comprise as little as 2% of the total surface of the material, the fusion source would not materially affect the surface chemistry for immobilization purposes.

Response to Arguments

6. Applicant's arguments filed 12/6/04 with respect to the rejection(s) of claim(s) 41, 43-44, 46-48, and 56-58 under 35 USC 103 over Yasukawa et al. or Lyles et al. in view of Koester et al. have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Yasukawa et al. or Lyles et al. in view of Arnold (See 35 USC 103 rejections above).

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Conclusion

Claims 41, 43-44, 46-48, and 56-58 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825.

The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641

12/10/04